

REMARKS/ARGUMENTS

Claims 1-71 remain pending herein.

The applicant hereby affirms the elections set forth in the Response to Restriction and Election of Species Requirements filed November 19, 2004.

Claim 16 has been amended as requested in the December 21, 2004 Office Action. It is respectfully requested that the U.S. PTO reconsider and withdraw the objection to claim 16.

Claim 63 has been amended to recite a method and depend from claim 1 or claim 11, and to further limit those claims by restricting the recited conditions. It is respectfully requested that the U.S. PTO reconsider and withdraw the objection to claim 63.

Claims 6 and 15 have been amended as requested in the December 21, 2004 Office Action. It is respectfully requested that the U.S. PTO reconsider and withdraw the objection to claims 6 and 15.

Claims 1-6, 8-23, 25-29, 63 and 64 were rejected under 35 U.S.C. 112, second paragraph. The December 21, 2004 Office Action contains an assertion that these claims are considered indefinite because the expressions "degenerative", as employed in the expressions "a degenerative disorder" and "related", as used in the expressions "a degenerative-related disorder", "a neurodegenerative-related disorder" and "related degenerative disorders", are not defined in the claims and the specification does not provide a standard for ascertaining the requisite qualitative nature of the "degeneration" or "relationship."

It is respectfully submitted that the specification, when read in the light of conventional knowledge in the art, would reasonably apprise persons of ordinary skill in the art as to the metes and bounds of the literal scope of the terms recited in the claims, to such an extent that a person of ordinary skill in the art could readily determine whether any particular

subject matter falls inside or outside the literal scope of each of the claims. It is respectfully noted that claims must be construed from the standpoint of a person skilled in the relevant art in determining whether they particularly point out the subject matter which is covered by the claim. In re Barr, Williams and Whitmore, 170 USPQ 330, (CCPA 1971).

Claims 63 and 64 have been amended to eliminate use of the expressions "Use in" and "Use of."

Accordingly, it is respectfully requested that the U.S. PTO reconsider and withdraw this rejection.

Claims 1-20, 22-29, 63 and 64 were rejected under 35 U.S.C. 112, first paragraph. The December 21, 2004 Office Action contains an assertion that while the specification is enabling for treating or slowing the progression of a degenerative or neurodegenerative disorder, the specification does not reasonably provide enablement for the *prevention* of a degenerative or neurodegenerative disorder. The Office Action further contains a statement that

... the objective truth of the statement that a degenerative or neurodegenerative disorder can be prevented is doubted because the art ... teaches that, at best, prevention of neurodegenerative diseases is merely a possibility and not a treatment outcome that can be accomplished with a reasonable degree of certainty.

(December 21, 2004 Office Action, page 9, lines 14-17).

The requirement that an invention have utility is found in 35 U.S.C. 101, and it is implicit in 35 U.S.C. 112, first paragraph. *In re Brana*, 34 USPQ2d 1436, 1439 (Fed. Cir. 1995). MPEP section 2107, subsection IV, notes that a rejection based on "lack of utility," whether grounded upon 35 U.S.C. 101 or 35 U.S.C. 112, first paragraph, rests on the same basis (i.e., the asserted utility is not credible). With regard to the utility requirement, the issue

is whether the applicants' assertions of utility are credible, and an assertion of operability is deemed to be credible unless (a) the logic underlying the assertion is seriously flawed, or (b) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. MPEP, § 2107.01, page 2100-38. Rejections under 35 U.S.C. 101 have been rarely sustained by Federal courts. Generally speaking, in these rare cases, the 35 U.S.C. 101 rejection was sustained either because the applicant failed to disclose any utility for the invention or asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature, or was wholly inconsistent with contemporary knowledge in the art. MPEP, page 2100-38.

It is respectfully submitted that there is no underlying logic made by the present applicant which is seriously flawed, and that the facts upon which the assertions of the utility of the present invention is based are not inconsistent with such logic. Moreover, it is submitted that in order for the present invention to function as disclosed, no scientific generally accepted scientific principles would be violated.

Accordingly, it is respectfully requested that the U.S. PTO reconsider and withdraw this rejection.

Claims 1-20, 22-29, 63 and 64 were rejected under 35 U.S.C. 102(b) over U.S. Patent No. 5,668,117 (Shapiro '117).

Shapiro '117 discloses a general object of treating neurological diseases and etiologically related symptomology by use of carbonyl trapping agents. According to Shapiro '117, the invention includes use of various co-agents which may facilitate glutathione activity, such as N-acetylcysteine, oxo-thiazolidine-carboxylate, timonacic acid, cysteamine, lipoamide derivatives such as malotilate (Kantec), sulfarlem (ADT), and oltipraz, "as these co-agents may further serve to improve the invention described in U.S. patent application Ser.

No. 08/026,617, filed Feb. 23, 1993, now abandoned." Accordingly, oltipraz is disclosed as being used as a co-agent together with a carbonyl trapping agents. In view of such disclosure, Shapiro '117 does not disclose administering to a patient a therapeutically effective amount of oltipraz, as encompassed by the present claims.

Accordingly, it is respectfully requested that the U.S. PTO reconsider and withdraw this rejection.

Claims 1-20, 22-29, 63 and 64 were rejected under 35 U.S.C. 102(b) over WO 98/27970 (WO '970), Stedman's Medical Dictionary and Remington's Pharmaceutical Sciences.

WO '970 discloses treating diseases or cellular damage caused by oxygen-containing free radicals, or of preventing or minimizing such damage, by administering one or more glutathione S-transferase elevating compounds. Among conditions in which free radical damage is implicated, WO '970 discloses several neurological conditions, e.g., Alzheimer's disease, Parkinson's disease, schizophrenia and tardive dyskinesia. Among compounds in the 1,2-dithiol-3-thione class, disclosed as being within the scope of compounds that increase the specific activity of glutathione S-transferase in cells of a patient is oltipraz. In order to arrive at administration of oltipraz to treat a condition encompassed by the present claims, one would have to make two specific selections from within two broad groups of subject matter disclosed in WO '970. Whenever selections are required in order to arrive at a particular combination of features, anticipation is not present.

Accordingly, it is respectfully requested that the U.S. PTO reconsider and withdraw this rejection.

Claims 1-20, 22-29, 63 and 64 were rejected under 35 U.S.C. 103(a) over Shapiro '117 or WO '970 in view of U.S. Patent No. 5,559,133 (Girijavallabhan '133).

Girijavallabhan '133 is apparently relied on in the December 21, 2004 Office Action for alleged disclosure of cyclodextrin. Accordingly, the disclosure in Girijavallabhan '133 relied on in the Office Action does not overcome the shortcomings of Shapiro '117 and WO '970 as those references are attempted to be applied against claims 1, 11 or 64, from at least one of which each of claims 2-10, 12-20, 22-29 and 63 each ultimately depend.

Accordingly, it is respectfully requested that the U.S. PTO reconsider and withdraw this rejection.

In view of the above, it is respectfully submitted that claims 1-20, 22-29, 63 and 64 are in condition for allowance.

If the Examiner believes that contact with Applicants' attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicant's attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,



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